REMARKS

This Amendment is responsive to the Office Action dated June 9, 2005. Applicant has renumbered original claim 36 (second occurrence) through original claim 53 to correct a claim numbering error. In particular, there were two occurrences of claim 36 in the original claim set. Claim 36 (second occurrence) through original claim 53 are now renumbered as claims 37-54. Claims 1-54 are pending. Claims 30-46 have been withdrawn from consideration. Claims 10, 17, 23 and 24 have been amended to correct minor formal errors.

Objection to Specification

In the Office Action, the Examiner objected to the Specification because of informalities regarding original claims 46-49 (now renumbered as claims 47-50). In particular, the Examiner asserted that the detailed description does not clearly set forth the structures that make up each of the means clauses in claims 47-50, and requested that Applicant clearly indicate which structures constitute which means.

Applicant respectfully traverses the objection. The specification clearly provides sufficient structure in correspondence to the mean-plus-function limitations set forth in claims 47-50. Although Applicant believe it is unnecessary to identify such structure in view of the clear support provided in the disclosure, set forth below is a brief discussion of corresponding structure for the convenience of the Examiner. Corresponding structure will be described by reference to paragraph numbers in corresponding U.S. published patent application no. 2002/0181875A1.

In regard to independent claim 47, the detailed description describes a controller 30 that controls timer 38 to time a lockout interval, and initiates timer 30 to count up to, or count down from, a lockout interval.[1] Controller 30 provides an exemplary means for initiating a timer to time a lockout interval upon issuance of a first dosage of a drug via an implantable drug delivery system, as set forth in claim 47.

As further described in the detailed description, an activation unit (10) includes input/output (I/O) interface 36 to receive user requests and to provide feedback to the user upon

[1] See, e.g., Paragraphs [0046] and [0049].

receiving such requests.[2] I/O interface 36 provides an exemplary means for receiving an input signal indicating a user request for a second dosage of the drug from the implantable drug delivery system, as set forth in claim 47.

In addition, controller 30 determines whether to issue a request signal to drug delivery system 4 via radio frequency (RF) telemetry 34.[3] RF telemetry 34 provides exemplary means for communicating an activation signal from an external activation device to the implantable drug delivery system in response to the input signal when the input signal is received after expiration of the lockout interval, as recited in claim 47.

Activation unit 10 determines whether the lockout interval has expired. If not, activation unit 10 indicates that the user has tried to activate a dose during the lockout interval.[4] Hence, activation unit 10 (or controller 30 within activation unit 10) provides exemplary means for rejecting the user request for the second dosage of the drug when the input signal is received prior to expiration of the lockout interval, as required by claim 47.

In regard to claim 48, the specification provides support for means for programmatically setting a lockout interval. For example, the lockout interval may be programmatically defined by a clinician via I/O interface 36.[5] I/O interface and controller 30 represent an exemplary means for programmatically setting a lockout interval.

In regard to claim 49, the specification provides support for means for receiving a response communication from the implantable drug delivery system and means for restarting the timer when the response communication indicates the implantable drug delivery system issued the second dosage of the drug. For example, activation unit 10 may also receive response signals from drug delivery system 4 via RF telemetry 34.[6] RF telemetry 34 provides exemplary means for receiving a response communication from the implantable drug delivery system, as required by claim 49.

As another example, upon activation of drug delivery system 4 in response to the user request, activation unit 10 restarts the lockout interval.[7] Activation unit 10 provides an

[2] See, e.g., Paragraph [0045].
[3] See, e.g., Paragraph [0046].
[4] See, e.g., Paragraph [0062].
[5] See, e.g., Paragraph [0046].
[6] See, e.g., Paragraph [0050].
[7] See, e.g., Paragraph [0039].

exemplary means for restarting the timer when the response communication indicates the implantable drug delivery system issued the second dosage of the drug, as required by claim 49.

The detailed description clearly describes structure corresponding to the various means limitations set forth in claims 47-50, as amended. The corresponding structure is not necessarily limited to the structure (and equivalents thereof) described above. Rather, the examples of corresponding structure are described above for purposes of illustration.

Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-29 and 46-54 under 35 U.S.C. 103(a) as being unpatentable over Boydman (US 5,069,668) in view of Fischell (US 4,731,051).

Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the elements defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Neither Boydman nor Fischell provides any teaching that would have suggested activation of an implantable drug delivery system by maintaining a timer to time a lockout interval, and rejecting a user request to activate an implantable drug delivery system prior to expiration of the lockout interval, as set forth in claims 1-16 and 22-29.

Similarly, contrary to the requirements of claims 17-21 and 47-54, Boydman and Fischell fail to disclose of suggest activation of an implantable drug delivery system by initiating a timer to time a lockout interval upon issuing a first drug dosage from the system, receiving an input signal indicating a user request for a second dosage, communicating an activation signal from an external activation device to the system when the input signal is received after expiration of the lockout interval, and rejecting the user request for the second dosage when the input signal is received prior to expiration of the lockout interval.

In the Office Action, the Examiner characterized Boydman as disclosing "a method and device for activating a drug delivery system that includes initiating a timer to time a lock out interval upon issuing a first dosage, receiving an input signal indicating a user request for a second dosage, rejecting the user request for the second dosage/flow rate change when received prior to expiration of the lock out interval and initiating the user request for the second dosage/flow rate change when received after expiration of the lock out interval."

The Examiner apparently recognized that Boydman does not disclose or suggest an implantable drug delivery system. In particular, with reference to claims 5-13, 17-21, 27-29 and 46-53, the Examiner acknowledged that Boydman fails to teach an external activation device in conjunction with an implantable drug delivery system. The Examiner cited Fischell, however as teaching an external activation device and implantable pump, and stated that the activation device limits the amount of drug the patient can administer.

The Examiner concluded that it would have been obvious "to incorporate the external activation device of Fischell into the system and method of Boydman." According to the Examiner, "the motivation for the combination would have been in order to enable the system and method of Boydman to be used with an ambulatory patient or one that desires free range of movement . . . thereby enhancing the patient's quality of life."

The Examiner's conclusion of obviousness is improper for several reasons. First, if Boydman were modified in view of Fischell, as proposed by the Examiner, the result would not conform to the requirements of Applicant's claims. Second, a vague desire to enhance a patient's quality of life provides nothing to suggest the specific modification necessary to arrive at the claimed invention. Third, neither Boydman, Fischell or any other art of record that would have suggested the desirability of modification to apply a lockout interval in an implantable drug delivery device.

Claims 1-4, 9-13, 14-16 and 22-26

In regard to independent claims 1 and 22, Boydman fails to suggest an implantable drug delivery system, as required in claim 1. On the contrary, the system described by Boydman is an external infusion pump that is not susceptible to implantation within a patient. Clearly, infusion pump (unit 10) is not implantable, as the patient is "hooked up" to such a unit in the recovery room of a hospital.[8] Boydman describes unit 10 for use on a post-operative patient[9] who recovers from anesthetic and regains consciousness.[10]

Therefore, if Boydman were modified to include an external activation unit per Fischell, the resulting device would not even be implantable. Moreover, it is unclear why one of ordinary

[8] Boydman, Col. 9, Lines 36-38.
[9] Boydman, Col. 9, Line 33.
[10] Boydman, Col. 9, Lines 65-66.

skill in the art would seek to add an external activation device to an infusion pump that is already external. Nor is there any teaching in Boydman or Fischell that would have suggested the necessary modifications to make the Boydman device implantable.

Conversely, there is also no teaching that would have suggested modification of the Fischell device, in view of Boydman, to conform to the requirements of the claimed invention. Fischell describes an implantable pump in combination with a patient programming unit (PPU) and a medication programming unit (MPU). According to Fischell, the MPU is used to set a basal delivery rate for drug administration. The PPU permits a patient to request half or full basal rate delivery. However, Fischell makes no mention of the use of a lockout interval, maintaining a timer to time a lockout interval, or rejecting a user request to activate an implantable drug delivery system prior to expiration of the lockout interval, as claimed.

Fischell describes an implantable programmable infusion pump (IPIP) electronic control means 21 that includes a "running integral rate limiting means 32 [which] is the principal safety feature contained within the electronic control means [21 of the IPIP]."[11] The running integral rate limiting means does not apply a lockout interval, and is not responsive to a user activation request. Instead, the rate limiting is provided within an implantable device to prevent a control means from delivering dosages that exceed a limit. In Fischell, there is no concept of a lockout interval, or rejection of a user request to activate an implantable drug delivery system prior to expiration of the lockout interval.

Dependent claims 2-16 and 23-29 are patentable for at least the reasons stated above with respect to independent claim 1, from which they depend.

In addition, in regard to claim 15, Boydman fails to describe adjusting the bolus amount in response to a user request. Nowhere is this element taught or suggested by Boydman. For example, Boydman states that a "'loading' or 'bolus' dose of analgesia is delivered to the patient at the start of system operation."[12] However, the patient is not able to modify the bolus amount. Therefore, Boydman provides no suggestion of adjusting the bolus amount in response to the user request, as required in claim 15.

[11] Fischell, Col. 7 Lines 10-12.
[12] Boydman, Col. 9, Lines 44-46.

Claims 5-8, 17-21, 27, 28 and 47-53

In regard to claims 5, 17, 27 and 47, neither Boydman nor Fischell discloses or suggests communicating an activation signal from the external activation device to the implantable drug delivery system in response to an input signal received after expiration of a lockout interval. In Boydman, rate limiting means are provided in the drug pump, and not by an external activation device. Similarly, the IPIP electronic control means 21 described by Fischell is provided within an implantable device, and not within an external activation device. Hence, there is no suggestion in Boydman or Fischell of communicating an activation signal from the external activation device to the implantable drug delivery system in response to an input signal when the input signal is received after expiration of the lockout interval, as required by claims 5, 17, 27 and 47, and the claims dependent on such claims.

In addition, in regard to claim 19, neither Boydman nor Fischell teaches or suggests communication of an activation signal from an external activation device to an implantable drug delivery system when an input signal is received after expiration of a lockout interval. Accordingly, these references likewise would not have suggested receiving a response communication from the implantable drug delivery system, and restarting a timer when the response communication indicates the implantable drug delivery system issued the second dosage of the drug. The running integral rate limiting means 32 in Fischell resides within the IPIP, and is not dependent on a response communication from the IPIP.

In regard to independent claim 51, neither Boydman nor Fischell teaches or suggests receiving a user request to activate an implantable drug delivery system, communicating an activation signal from an external activation device to the implantable drug delivery system in response to the user request, and activating the implantable drug delivery system in response to the activation signal. Again, Boydman does not even contemplate an external activation device that communicates an activation signal to an implantable drug delivery system. The PPU in Fischell is "limited in its programming capability," and permits a patient to "merely choose to deliver a full or half basal rate, select on [sic] of the several pre-programmed supplemental prescription schedules, inhibit pump activity, or countermand previous directives." Therefore, Boydman and Fischell, taken alone or in combination, fail to suggest the features recited in claim 51.

Dependent claims 6-8, 18-21, 28, 48-50 and 52-54 are patentable for at least the reasons stated above with respect to the respective independent claims 1, 17, 47 and 51 from which they depend.

With further regard to the dependent claims, Applicant does not acquiesce to any of the Examiner's rejections or characterizations of the prior art, and reserves the right to present additional arguments with respect to any features of the dependent claims not specifically addressed in the Office Action or this response.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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